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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,031	12/01/2003	Oleg Shikhman	INE-0061D3	4709
23413	7590	09/13/2006	EXAMINER	
CANTOR COLBURN, LLP 55 GRIFFIN ROAD SOUTH BLOOMFIELD, CT 06002			SONNETT, KATHLEEN C	
			ART UNIT	PAPER NUMBER
			3731	
DATE MAILED: 09/13/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/726,031

Applicant(s)

SHIKHMAN ET AL.

Examiner

Kathleen Sonnett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 18-25 is/are rejected.
- 7) ☒ Claim(s) 16 and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Habermeyer et al. (U.S. 5,575,801). Habermeyer et al. discloses a suture loading assembly for threading suture material through a surgical instrument, the suture loading assembly comprising a body (36), an attaching body member (18) extending from the body to the surgical instrument and a flexible loop (see fig. 11) extending from a distal end of the body. Regarding 5, the cap portion is the enlarged handle portion seen in Fig. 11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Habermeyer et al. in view of Johnson (U.S. 4,779,616). Habermeyer et al. discloses the invention substantially as stated above but is silent on the material of the loop and the connection of the loop to the body.

However, Johnson discloses that it is old and well known in the art to include a wire loop that connects into the body (10) of a suture loading assembly for threading suture through an instrument. The wire is resilient and allows the loop to collapse as it passes through a cannula. The suture loading assembly of Habermeyer et al. is used to thread suture through cannula (34). The body includes a bore through which the loop extends (see fig. 3). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Habermeyer et al. to include a suture loading assembly that includes a bore in the body from which a wire loop extends as made obvious by Johnson since the wire allows the loop to collapse when pushed or pulled through a cannula.

Regarding claim 10, the modified device of Habermeyer et al. does not expressly disclose a plug used to retain the wire within the body but instead discloses swaging the wire within the body to hold the wire in place (see col. 2 lines 23-26 of Johnson). At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a plug to retain the wire within the body because Applicant has not disclosed that the use of such a plug provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the modified device of Habermeyer et al. and applicant's invention to perform equally well with either the claimed plug or the swaging made obvious by Johnson because both perform the same function of connecting the wire loop to the body. Therefore, it would have been prima facie obvious to further modify Habermeyer et al. to obtain the invention as specified in claim 10 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of modified Habermeyer et al.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Habermeyer et al. in view of Durlacher et al. (U.S. 5,562,664). Habermeyer et al. discloses the invention

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substantially as stated above, but fails to disclose two legs on the attaching member that extend from the body, an inner portion of each leg curved to accept a cylindrical member of a surgical instrument wherein the attaching member is slidable along the cylindrical member of the surgical instrument.

However, Durlacher et al. discloses that it is old and well known in the art to use an attaching member (14) that includes two legs (each half of element 11) each having an inner portion curved to accept a cylindrical member. The attachment member (17) of Habermeyer et al. includes a cylindrical bore through which a tubular instrument is slid. With this arrangement, the mount must be slide onto device (16) before the distal end (12) is inserted into the body. Using a hinged mount such as the one taught by Durlacher et al. allows a tubular device to be snapped into the mount which would allow the mount to be put on or taken off at any point during the surgery without having to remove the distal end (12) of (16) from the body.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Habermeyer et al. in view of Durlacher et al. (U.S. 5,562,664) as applied to claim 3 above, and further in view of Converse (U.S. 3,361,382). Modified Habermeyer et al. discloses the invention substantially as stated above, but fails to disclose an indented area for forming a finger grip.

However, Converse discloses that it is old and well known in the art of hand held suturing devices to include finger grips on handles which are indents (see Fig. 3). The finger grips allow the handle to be comfortably and naturally grasped by the doctor during the suturing operation (col. 2 lines 40-42). An indented area would similarly allow a user to more easily grasp member trigger member (15) and the other leg in order to compress the trigger to release the device connected to the mount (see fig. 1 of Durlacher et al.). Therefore, it would have been obvious to one ordinary skill in the art to modify the device of Habermeyer et al. to include

indented areas on the outer portion of each leg as made obvious by Converse in order to gain the advantage of being more user-friendly.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Habermeyer et al. in view of Converse (U.S. 3,361,382). Habermeyer et al. discloses the invention substantially as stated above, but fails to disclose finger grips comprising indents in sides of the cap.

However, Converse discloses that it is old and well known in the art of hand held suturing devices to include finger grips on handles which are indents (see Fig. 3). The finger grips allow the handle to be comfortably and naturally grasped by the doctor during the suturing operation (col. 2 lines 40-42). Therefore, it would have been obvious to one ordinary skill in the art to modify the device of Habermeyer et al. to include finger grips on the cap as made obvious by Converse in order to gain the advantage of being more user-friendly.

Claims 11-13, 18-19, 21-23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Habermeyer et al. in view of Sauer et al. (U.S. 5,520,702). Habermeyer et al. discloses a suture securing instrument and a suture loading assembly, the suture securing instrument comprising an elongated tubular portion having a distal and a proximal end, the proximal end attached to a handle assembly, the suture loading assembly comprising a body, an attaching member (18) extending from the body for attaching the body to the elongated tubular portion of the suture securing instrument and a flexible loop extending from a distal end of the body (see fig. 11). Habermeyer et al. fails to disclose a distal end on the suture-securing instrument that includes a ferrule-accepting opening wherein the loop is threaded through the opening.

However, Sauer et al. discloses that it is old and well known in the art to include such an opening in a suture-securing instrument. Sauer et al. further discloses threading the loop

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through the opening such that a ferrule can be placed around the suture ends (fig. 4,5). Sauer et al. discloses that using a ferrule is advantageous to knotting suture in order to provide tension since knotting can be both time consuming and burdensome due to the difficult maneuvers and manipulation which is required by the surgeon (col. 2 lines 3-6). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Habermeyer et al. to include a ferrule accepting hole through which the loop is threaded as made obvious by Sauer et al. in order to gain the advantages associated with not having to knot the suture to provide tension.

Regarding claim 13, the attaching member is slidable along the tubular portion of the suture-securing instrument since (17) is slid over (16) prior to use.

Regarding claim 18, the suture-securing instrument comprises an aperture in the elongated tubular portion, the aperture located proximally of the ferrule-accepting opening, the flexible loop threaded through the aperture prior to threading through the ferrule-accepting opening. The ferrule is placed at an angle as seen in Fig. 3 and therefore, aperture (76) is proximal to the ferrule opening.

Regarding claim 19, the ferrule is positioned within the ferrule-accepting opening, the flexible loop threaded through the ferrule.

Regarding claim 25, Sauer et al. further discloses the use of a suture loading assembly and ferrule with a cutting and crimping device. It would be obvious to further modify Habermeyer et al. to include the cutting and crimping device as made obvious by Sauer et al. in order to have a way of cutting excess suture and crimping the ferrule so that it is tightened around the suture without having to provide a separate instrument.

Regarding claim 21, Habermeyer et al. discloses the method substantially comprising mounting a suture loading assembly upon a tubular portion of the suture securing instrument but fails to disclose threading a flexible loop extending from the suture loading assembly through a

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ferrule within a distal end of the suture loading assembly. However, as stated above, Sauer et al. discloses that using a ferrule is advantageous to knotting suture in order to provide tension since knotting can be both time consuming and burdensome due to the difficult maneuvers and manipulation which is required by the surgeon (col. 2 lines 3-6). Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Habermeyer et al. to include threading a loop through a ferrule within a distal end of the suture loading assembly as made obvious by Sauer et al. in order to gain the advantages associated with not having to knot the suture to provide tension.

Regarding claims 21-23 see fig. 4 and 5.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Habermeyer et al. in view of Sauer et al. as applied to claim 11 above, and further in view of Durlacher et al. (U.S. 5,562,664). Habermeyer et al. discloses the invention substantially as stated above, but fails to disclose two legs on the attaching member that extend from the body, an inner portion of each leg curved to accept a cylindrical member of a surgical instrument wherein the attaching member is slidable along the cylindrical member of the surgical instrument.

However, Durlacher et al. discloses that it is old and well known in the art to use an attaching member (14) that includes two legs (each half of element 11) each having an inner portion curved to accept a cylindrical member. The attachment member (17) of Habermeyer et al. includes a cylindrical bore through which a tubular instrument is slid. With this arrangement, the mount must be slide onto device (16) before the distal end (12) is inserted into the body. Using a hinged mount such as the one taught by Durlacher et al. allows a tubular device to be snapped into the mount which would allow the mount to be put on or taken off at any point during the surgery without having to remove the distal end (12) of (16) from the body.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Habermeyer et al. in view of Durlacher et al. (U.S. 5,562,664) as applied to claim 14 above, and further in view of Converse (U.S. 3,361,382). Modified Habermeyer et al. discloses the invention substantially as stated above, but fails to disclose an indented area for forming a finger grip.

However, Converse discloses that it is old and well known in the art of hand held suturing devices to include finger grips on handles which are indents (see Fig. 3). The finger grips allow the handle to be comfortably and naturally grasped by the doctor during the suturing operation (col. 2 lines 40-42). An indented area would similarly allow a user to more easily grasp member trigger member (15) and the other leg in order to compress the trigger to release the device connected to the mount (see fig. 1 of Durlacher et al.). Therefore, it would have been obvious to one ordinary skill in the art to modify the device of Habermeyer et al. to include indented areas on the outer portion of each leg as made obvious by Converse in order to gain the advantage of being more user-friendly.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Habermeyer et al. in view of Sauer et al. as applied to claim 11 above, and further in view of Wenstrom Jr. (U.S. 5,800,447). The modified device of Habermeyer et al. discloses the invention substantially as stated above, but fails to disclose that the flexible loop on the suture loading assembly is a wire bent into a diamond shape.

However, Wenstrom Jr. discloses that it is old and well known in the art to use wire bent into a diamond shape (see fig. 1; col. 5 line 63) to form the flexible loop on a suture loading assembly. Wenstrom Jr. discloses that this allows the loop to collapse when pulled through a catheter and self-expand when in an open environment (col. 5, lines 7-18). Therefore, it would have been obvious to one of ordinary skill in the art to further modify the device of Habermeyer et al. to include a suture loading assembly that has a wire bent into a diamond shape for the

flexible loop as made obvious by Wenstrom Jr. so that the device may collapse when pulled through a small bore such as the ferrule and self-expand when not impeded.

Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer et al. in view of Sauer et al. in view of Schneebaum et al. (U.S. 5,423,830). Sauer et al. discloses the method of threading a suture securing instrument comprising threading a flexible loop extending from the suture loading assembly through a ferrule within a distal end of the suture loading assembly, inserting suture material through the flexible loop and pulling the flexible loop proximally until the suture material is threaded through the ferrule. Sauer et al. fails to disclose mounting a suture loading assembly upon a tubular portion of the suture-securing instrument and sliding the suture loading assembly proximally along the tubular portion of the securing instrument.

However, Schneebaum et al. discloses that it is old and well known to mount one medical device to another when the devices are used in conjunction with one another. In particular, Schneebaum et al. discloses mounting a snaring device (76) onto another medical device (78), with which it is used in conjunction. In the device of Schneebaum et al., the loop of the snare is pulled proximally by sliding (72) proximally along the tubular portion of (58) of the endoscope. This is advantageous in endoscopic procedures since space at the surgical site is generally limited. Sauer et al. discloses the use of a suture loading assembly comprising a loop to pull suture proximally along the tubular portion of the suture-securing instrument (see fig. 4, 5, and 7). Using the teachings of Schneebaum et al., it would be obvious to one of ordinary skill in the art to modify the method of Sauer et al. to include mounting the suture-securing instrument onto the tubular portion of the suture securing instrument in order to gain the advantage of attaining as small of a profile for the two devices used in conjunction as possible.

Allowable Subject Matter

Claims 16 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS
8/24/2006


GLENN K. DAWSON
PRIMARY EXAMINER